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Original Article

A study of the value of trabecular bone score in fracture risk assessment of postmenopausal women

Alireza Mirzaei [a], Seyed Adel Jahed [b], Marzieh Nojomi [c], Alireza Rajaei [d], Mozhdeh Zabihiyeganeh [a, *]

[a] Bone and Joint Reconstruction Research Center, Shafa Orthopedic Hospital, Iran University of Medical Sciences, Tehran, Iran
[b] Diabetes Advisory Committee, Gabric Diabetes Education Association, Tehran, Iran
[c] Preventive Medicine and Public Health Research Center, Department of Community and Family Medicine, School of Medicine, Iran University of Medical Sciences, Tehran, Iran
[d] Department of Rheumatology, Loghman Hospital, Shahid Beheshti University of Medical Sciences, Tehran, Iran

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ABSTRACT

Objective: Trabecular Bone Score (TBS) is an index of bone microarchitecture that provides additional skeletal information to areal Bone Mineral Density (aBMD). Recently TBS data has been used to optimize the Fracture Risk Assessment Tool (FRAX) predictive value. The aim of this study was to evaluate the clinical value of TBS on FRAX algorithm.

Materials and Methods: Among total of 358 postmenopausal Iranian women (mean age 61.3 ± 9.5 years) tested for aBMD and TBS, 184 osteopenic women were identified. Thoracolumbar spine X-ray done in all participants revealed twenty-one vertebral fractures. For the osteopenic group, FRAX and TBS adjusted FRAX (FRAX-TBS) were calculated and compared.

Results: Mean TBS of the patients was 1.31 (±0.11). A significant correlation was found between TBS and spine aBMD ($r = 0.50$, $p < 0.001$) and TBS and femoral neck aBMD ($r = 0.37$, $p < 0.0001$). A strong positive correlation was observed between aBMD adjusted FRAX and FRAX-TBS in predicting the risk of major osteoporotic fracture ($r = 0.90$, $p < 0.0001$), and hip fracture ($r = 0.97$, $p < 0.0001$). According to the area under the receiver operating characteristics curve, the predictive value of the three different models using aBMD, TBS, and combination of aBMD and TBS were similar (0.765, 0.776, and 0.781, respectively; $p = 0.19$). The proportion of the women needed treatment remained unchanged using FRAX or FRAX-TBS.

Conclusion: This study showed no clinical benefit for TBS in postmenopausal women. Adding TBS data to aBMD or FRAX neither improved aBMD predictive value for vertebral fracture nor changed the decision on treatment based on FRAX.

Introduction

Osteoporosis as a leading cause of bone fragility fractures, is a major public health problem mostly affecting postmenopausal women and aging individuals of both sexes [1,2]. In 1990, the prevalence of fragility fracture was about 1.5 million worldwide and it is estimated to reach three millions by 2025 [3]. Osteoporotic fragility fractures lead to severe mortality and morbidity, a significant burden on society in general, and a huge economic impact [4]. Osteoporosis is a common health problem among Iranian population, as well [5].

Considering osteoporosis as a skeletal disorder characterized by both low bone density and microarchitectural deterioration, it seems logic that to prevent osteoporotic fracture we need to pay attention to the both surrogates of bone strength [6]. Until recently, areal bone mineral density (aBMD) was the only method used in assessment of osteoporosis and fracture risk. This approach resulted in an important clinical problem: more than half of the fragility fractures occurred in people with aBMD above the diagnostic threshold of osteoporosis [7]. On the other hand, treating everyone with the T-scores between −1 and −2.5 is neither medically nor economically appropriate. Fracture risk assessment tool (FRAX) is a supportive software in the field of osteoporosis management

* Corresponding author. Shafa Orthopedic Hospital, Baharestan Sq, Tehran, Iran. Fax: +98 21 33542020.
E-mail address: mozhdehzabihi@gmail.com (M. Zabihiyeganeh).

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initially designed to aid in identifying previously untreated patients with low bone density who are at a higher risk of fragility fracture; in fact it particularly provides a quantitative estimate of absolute fracture risk to decide which osteopenic patient most likely benefits from treatment [8].

Trabecular bone score (TBS) is an indirect indicator of bone microarchitecture. It is a texture measurement that quantifies local variations in gray level distribution from dual-energy X-ray Absorptiometry (DXA) and is significantly correlated with three dimensional parameters of bone microarchitecture, independently of aBMD [9–12]. Given the importance of bone microarchitecture in the evaluation of fragility fractures, TBS has been recently added to FRAX. Considering bone microarchitecture in combination with aBMD and other risk factors, TBS adjusted FRAX (FRAX-TBS) provides its users a 10-year percentage of the risk of hip fracture (HF) and major osteoporotic fracture (MOF) [13].

Here we assessed the bone microarchitecture of postmenopausal Iranian women using TBS. We aimed to compare their FRAX-TBS with the usual aBMD based FRAX in order to find if adding TBS could affect the fracture risk assessment in our population.

Materials and methods

In a cross-sectional study, a number of 358 postmenopausal women indicated for osteoporosis screening were recruited from Rheumatology clinic of Resalat General Hospital, Tehran, Iran. The patients were referred to densitometry ward for aBMD and TBS evaluation. Exclusion criteria included bisphosphonates or any osteoporosis drugs consumption within the past two years, a history of Cushing's syndrome, malabsorption syndrome, liver failure, creatinine clearance <30 mL/min, or any chronic disorders of mineral metabolism. Women with type 2 diabetes were also excluded from the study. Since type 1 diabetes is considered as secondary osteoporosis in FRAX algorithm, we did not consider it in our exclusion criteria. In addition, since TBS can only be computed for patients with Body Mass Index (BMI) in range of 15–37 kg/m^2, only such postmenopausal women were included. Women were considered postmenopausal if they had amenorrhea for more than one year.

Thoracolumbar spine X-ray was obtained to evaluate the vertebrate fracture using the semi quantitative approach developed by Genant et al. [14].

Dual-energy X-ray absorptiometry (DXA) and TBS

aBMD of the spine (L1-L4) and femoral neck were evaluated using a DXA machine (Hologic Discovery). Bone mineral density was expressed in mg/cm^2 and T-score. T-score > −1, −1 to −2.5 and <−2.5 was considered as normal, osteopenic and osteoporotic, respectively.

TBS evaluation was performed along with aBMD evaluation. Anteroposterior (AP) spine acquisitions were implemented to evaluate TBS for L1–L4. TBS calculation was performed by TBS iNsight software (version 2.2; Medimaps, Geneva, Switzerland). TBS was assessed by determining the variogram of the trabecular bone projected image, calculated as the sum of the squared gray-level differences between pixels at a specific distance and angle. Subsequently, TBS was computed as the slope of the log–log transform of this variogram [12]. The average value of the individual measurements for L1–L4 represents the lumbar spine TBS (unit less). TBS results were classified as Degraded (<1.2), Partial degraded (1.2–1.35), and Normal (>1.35).

FRAX

Calculations of MOF and HF risk were performed using recently released Iranian aBMD adjusted FRAX (FRAX-BMD) online software (www.shefac.uk/FRAX). The clinical risk factors included were sex, age, weight, previous fracture, parental hip fracture, smoking, glucocorticoids consumption, alcohol consumption, rheumatoid arthritis and secondary osteoporosis. National Osteoporosis Foundation (NOF) cutoff values of 20% for MOF risk and 3% for HF risk were considered as high absolute 10 years risk of fracture [15].

TBS adjusted FRAX (FRAX-TBS)

In order to evaluate the effect of TBS on vertebral fragility fracture risk and to decide who may mostly benefit from pharmaceutical treatment, FRAX algorithm was calculated for osteopenic women before and after adjustment on TBS. Since osteoporotic patients are indicated for pharmaceutical treatment regardless of their fragility fracture risk, FRAX was not calculated for that group. In addition, normal individual are not indicated for pharmaceutical treatment. As a result, FRAX was not assessed for this group either.

Statistical analysis

IBM SPSS statistics version 21.0.1 (SPSS Inc., Chicago, IL, USA) and Stata software were used for data analysis. The sample size was estimated using sample size calculator for multiple regression models (http://www.danielsoper.com/statcalc/calculator.aspx?id=1). With a statistical power of 0.80, probability level of 0.05, and 10 predictors, the sample size was estimated almost 350. During the study period, we recruited 358 subjects. Pearson's/Spearman's correlation coefficients were calculated to assess association between numeric variables. Independent sample T-test or Mann–Whitney U and chi-square tests were used to assess differentiation of means and percentages across groups respectively. In order to assess means across more than two groups, Analysis of Variance (ANOVA) was used. Comparison of the proportion of patients needing a therapeutic intervention before and after TBS adjustment of FRAX was performed using McNemar's test. In order to evaluate the predictive effect of aBMD and TBS adjusted with age and BMI on vertebral fracture, binary multiple logistic regressions was used. Finally, in order to show the fracture predictive validity of spine aBMD (Model 1), spine TBS (Model 2) and their combination (Model 3), adjusted for age and BMI, Receiver Operating Characteristic Curve (ROC) was used. Area under the curve (AUC) was tested using chi-square test in Stata software. Significance level was considered as 0.05.

Results

From a total of 358 postmenopausal Iranian women, mean age of 61.3 ± 9.5 years, ninety-nine osteoporotic, 184 osteopenic and 75 normal women were identified. The mean spine and femoral neck aBMD were 882 ± 134 mg/cm^2, and 692 ± 114 mg/cm^2, respectively. Their corresponding mean T-scores were −1.51 ± 1.21 at lumbar spine, and −1.48 ± 0.98 at femoral neck region.

FRAX-BMD and FRAX-TBS have also been computed and the data have been shown in Table 1.

The mean TBS was 1.31 ± 0.11, ranging from 0.95 to 1.6. TBS value was significantly different across a BMD status ($p < 0.0001$). Post Hoc tests demonstrated that TBS value was also significantly different between all possible pairs of aBMD status ($p < 0.0001$).

According to TBS status, the bone microarchitecture was degraded in 45 (12.6%), partially degraded in 176 (49.1%), and normal in 137 (38.3%) postmenopausal women.

Table 1
Demographic and densitometric characteristics of the patients.

Variable	Mean±SD
Age (year)	61.3 ± 9.5
Menopausal age (year)	48.8 ± 4.1
Height (cm)	155.3 ± 6.6
Weight (kg)	69 ± 11.6
BMI (kg/m^2)	28.5 ± 4.5
L1–L4 T score	−1.51 ± 1.21
Femoral neck T score	−1.48 ± 0.98
L1–L4 TBS	1.31 ± 0.11
FRAX-BMD, MOF	4.3 ± 2.1
FRAX-BMD, HF	0.8 ± 0.96
FRAX-TBS, MOF	4.7 ± 2.4
FRAX-TBS, HF	0.9 ± 0.99

BMI: body mass index, TBS: trabecular bone score, aBMD: areal bone mineral density, FRAX-BMD: BMD adjusted FRAX, FRAX-TBS: TBS adjusted FRAX, MOF: major osteoporotic fracture, HF: hip fracture.

Among 75 postmenopausal women with normal aBMD, two (3%), 21 (28%), and 52 (69%) degraded, partially degraded and normal TBS were identified, respectively. In the osteopenic group, 16 (9%), 100 (54%), and 68 (37%) cases showed degraded, partially degraded and normal TBS values, respectively. From ninety-nine osteoporotic women, 27 (27), 55 (56%), and 17 (17%) cases found having degraded, partially degraded and normal TBS status, respectively (Table 2).

TBS was positively correlated with spine and femoral neck aBMD ($r = 0.50$, $p < 0.0001$, and $r = 0.37$, $p < 0.0001$; respectively). Significant negative correlation was observed between TBS and the age of our cohort ($r = -0.38$, $p < 0.0001$). Spinal and femoral neck aBMD were also negatively correlated with age of participants ($r = -0.15$, $p = 0.003$, and $r = -0.33$, $p < 0.0001$, respectively).

Based on FRAX or FRAX-TBS algorithm, none of osteopenic women had MOF risk of more than 20%. Regarding HF, using each of FRAX or FRAX-TBS algorithm detected the same 5 (3%) women of the osteopenic group as high risk for HF ($p = 1$).

Strong positive correlations were observed between FRAX-BMD and FRAX-TBS in predicting osteoporotic fracture risks (Fig. 1).

A total of twenty-one vertebral fragility fractures were identified in the study participants. While the majority of the fracture positive women were found in the partially degraded group, two cases were classified in the normal TBS group (Table 3). The mean TBS value of the fracture negative women was significantly higher than the fracture positive cases (1.32 ± 0.11 versus 1.24 ± 0.09, respectively, $p = 0.002$).

While only one fracture occurred in a woman with normal aBMD, the majority of the other twenty fractures found in the osteoporotic group (Table 4). The mean spine aBMD of patients without fracture was significantly more than patients with fracture (888 ± 131 mg/cm^2 versus 794 ± 136 mg/cm^2, respectively, $p = 0.003$).

Both aBMD and TBS were significant predictors of vertebral fracture after adjustment for age and BMI ($p = 0.008$ and 0.01, respectively) (Table 5).

Table 2
Distribution of TBS status according to aBMD status of the patients.

aBMD status	TBS status			Total
	Degraded	Partially degraded	Normal	
Osteoporosis	27 (27)	55 (56)	17 (17)	99 (100)
Osteopenia	16 (9)	100 (54)	68 (37)	184 (100)
Normal	2 (3)	21 (28)	52 (69)	75 (100)
Total	45 (13)	176 (49)	137 (38)	358 (100)

Data denoted as number (%). TBS: trabecular bone score, aBMD: areal bone mineral density.

For the patients with vertebral fracture, ROC curve was depicted for three different age and BMI adjusted models including spine aBMD, TBS, and combination of spine aBMD and TBS. The obtained areas under the curve values were 0.765 ($p < 0.0001$), 0.776 ($p < 0.0001$), and 0.781 ($p < 0.0001$), respectively (Fig. 2). Although a trend for better fracture prediction using combination model was found, the difference was not significant ($p = 0.19$).

Discussion

TBS as an index of bone microarchitecture has been recently included in FRAX algorithm. Adding TBS to FRAX software, as a complementary factor of fracture prediction might be considered as a valuable approach to optimize FRAX algorithm and lessen its potential pitfalls [16–19].

The present study demonstrates the role of TBS in fracture risk assessment in 358 Iranian postmenopausal women from an outpatient clinic. Based on our findings, the proportion of patients who needed therapeutic intervention did not change after FRAX adjustment on TBS. It may be explained at least in part by the fact that mean FRAX MOF and mean FRAX HF in our cases were about 4% and less than 1% respectively. Considering the frank difference of our patients' FRAX with the established cut points for treatment of 20% and 3% respectively, it is logically expected not to reach a considerable change even after adjustment on TBS [6].

As a rather new point of interest in the field of osteoporosis, the number of studies in assessing the potential optimizing effect of TBS on predictive value of FRAX for fracture is increasing but still there is no consensus in this regards [20–22]. It seems that the debate is mainly due to lack of enough convincing evidences from well-designed studies with focus on TBS adjustment of FRAX as the primary end point. The current available data have been mainly resulted from studies on heterogeneous population regarding age, sex, bone microarchitecture, type of fracture assessed, and duration of possible follow up. In a meta-analysis by McCloskey done on 17,809 men and women in fourteen prospective population-based cohorts, TBS found to be a significant predictor of fracture risk independently of FRAX [13]. Unlike McCloskey's finding, we found no positive effect from TBS adjustment of FRAX on prediction of fracture but we should pay attention that there was only a small increase of the prediction in the mentioned study. The primary research question in the recent study by Couraud et al. was very similar to our study, although it was done in an inpatient setting of high risk patients for osteoporosis with fracture [22]. Similar to our findings they showed that the proportion of patients at high risk of fracture was similar using FRAX or FRAX adjusted on TBS. In a subgroup analysis in the age category group of more than sixty years old, they found a small increase in the percentage of patients needed therapeutic intervention using FRAX-TBS. We could not perform such a subgroup analysis because the number of fractures in our study was not comparable to Couraud's study. Boutroy et al. in OFFLEY study directly focused on the role of TBS on fracture prediction [10]. Our study is similar to the OFFLEY in its included postmenopausal participants and their lumbar T-score. Both studies showed similar odds ratios of TBS or BMD in prediction of fracture, equality of TBS and BMD in fracture risk prediction, and no added value for combination of BMD and TBS in that regard. Our study was different with the OFFLEY in some points: they did not use FRAX-TBS but we did, they could follow the patients for about seven years and could pick up more fractures comparing to our results. Mildly higher age of the patients at inclusion time may be another explanation for their more fractures found. The recent publication in this field by Su et al. was performed on elder Chinese men and women to evaluate the effect of TBS on FRAX [21]. Similar to our results they did not reach any significant benefit from adding TBS to FRAX in

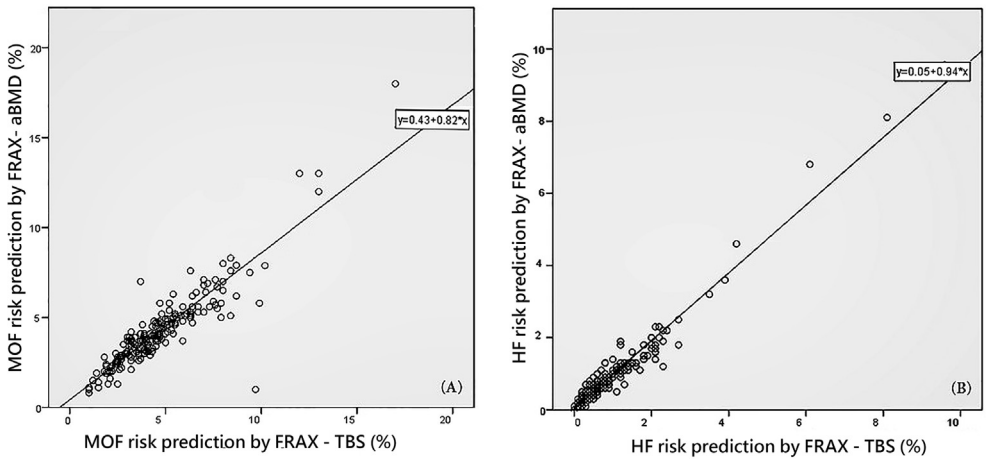

Fig. 1. Scatter plots of the correlation between aBMD - FRAX and FRAX-TBS for prediction of (A) MOF risk ($r = 0.90$, $p < 0.0001$), (B) HF risk ($r = 0.97$, $p < 0.0001$). aBMD: areal bone mineral density, FRAX: Fracture Risk Assessment Tool, TBS: trabecular bone score, MOF: major osteoporotic fracture, HF: hip fracture.

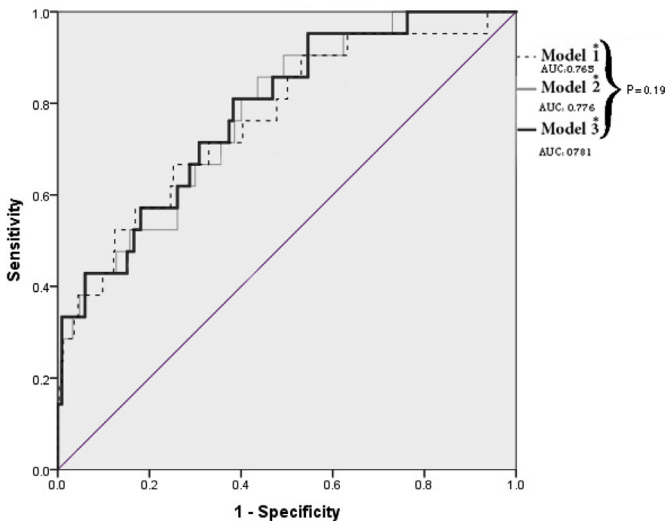

Fig. 2. Receiver operating characteristics curve analysis of different models for prediction of vertebral fracture. All modes have been adjusted for age and body mass index. Model 1: spine aBMD, Model 2: TBS, Model 3: combination of aBMD and TBS. aBMD: areal bone mineral density, TBS: trabecular bone score * $p < 0.00001$.

Table 3
Distribution of fragility fractures based on TBS status of the patients.

TBS status	Fracture		Total
	No	Yes	
Degraded	41 (91.1)	4 (8.9)	45 (100)
Partially degraded	161 (91.5)	15 (8.5)	176 (100)
Normal	135 (98.5)	2 (1.5)	137 (100)
Total	337 (94.1)	21 (5.9)	358 (100)

Data denoted as number (%). TBS: trabecular bone score.

postmenopausal women. However, using specific intervention thresholds, FRAX-TBS brought about 5% overall correct reclassification for MOFs prediction than FRAX alone in Chinese men.

We could also demonstrate a significant but moderate correlation between TBS and aBMD in accordance with other studies [10,23]. In spite of this agreement between the two models we should pay attention to possible pitfalls of each algorithm. One of the main well known limitations of BMD is its error in elder people who may frequently suffer from lumbar osteoarthritis [24]. Using

Table 4
Distribution of fragility fractures based on aBMD status of the patients.

aBMD status	Fracture		Total
	No	Yes	
Osteoporosis	84 (84.8)	15 (15.2)	99 (100)
Osteopenia	179 (97.3)	5 (2.7)	184 (100)
Normal	74 (98.7)	1 (1.3)	75 (100)
Total	337 (94.1)	21 (5.9)	358 (100)

Data denoted as number (%). aBMD: areal bone mineral density.

Table 5
Logistic regression analysis showing the fracture predictive values of aBMD and TBS.

Factor	Odds Ratio	95% CI	p value
TBS	1.58	1.27–1.76	0.003
TBS adjusted for age and BMI	1.47	1.18–1.69	0.01
aBMD	1.68	1.48–1.81	0.001
aBMD adjusted for age and BMI	1.61	1.42–1.77	0.008

aBMD: areal bone mineral density, TBS: trabecular bone score, CI: confidence interval.

TBS may theoretically correct this pitfall. During our study we noticed that two of our patients presented with normal BMD but fully degraded TBS. When we reviewed their profiles, severe osteophytes were evident in their spines X-rays, which could explain their false positive normal BMD. Although TBS may have clarified their real bone architecture for us, still there is a debate on the importance of this finding in routine daily practice. In fact up to this time there is no answer to the important clinical question on how to manage a person with good BMD but poor TBS.

The current study carries some limitations. Having no data registry system for osteoporotic patients prevented us from access to reliable fracture data and their proper follow. The number of fractures was rather low in our study. It might be due to different factors: our patients' younger age comparing other studies, outpatient setting for recruitment, and lack of established fracture liaison service.

Conclusion

This study showed no clinical benefit for TBS in postmenopausal women. Adding TBS data to aBMD or FRAX neither improved aBMD predictive value for vertebral fracture nor changed the decision on treatment based on FRAX.

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